

PROPOSED LABELING FOR THE DEVICE

THE MOSES EXPRESS APPLIANCE



Clinician Instruction Booklet

Caution: *Federal (U.S.) law restricts this device to sale by or on the written order of a licensed physician or dentist*

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INDICATIONS FOR USE

The Moses Express appliance is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea.

For prescription use only (RX only)

Part 21 CFR 801 subpart D

IMPORTANT SAFEGUARDS

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance:

WARNING: means there is a possibility of injury to your self

NOTE: indicates points of particular interest for more efficient and convenient operation

CONTRINDICATIONS: This device is contraindicated for patients with loose teeth, loose dental work, numerous missing teeth, dentures or other oral conditions that would be adversely affected by wearing an intraoral dental device which maintains the jaws in a protrusive jaw position. The Moses Express appliance is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.

PRODUCT DESCRIPTION

The Moses Express appliance is a dental device in the category of mandibular advancement device. The Moses Express is a dual-layer oral mouthpiece. The inner layer softens in hot water, between 180-185° Fahrenheit and takes the shape of the posterior teeth for a snug comfortable fit. The outer layer remains stable in the simmering water and maintains the Moses Express' shape. It is customized to the patient's mouth based on the predetermined maxillo-mandibular relationship and is fit over maxillary and mandibular customized vacuum formed retainers. It is fit to the patient by a trained dentist.

The device characteristics of The Moses Express appliance are as follows:

- Maxillary and mandibular customized vacuum formed retainers (.3 mm thick)
- An interarch component, customizable to fit over the maxillary and mandibular teeth
- The prescribed protrusive jaw position is maintained by the labial flanges and by impressions of the maxillary and mandibular arches covered by retainers and processed into the interarch component
- By supporting the mandible in a protrusive jaw position, The Moses Express appliance passively advances the tongue
- There is an open area between the upper and lower cuspids vertically that is approximately 2-8 mm vertically.
- This open area is to facilitate a forward tongue position against the lips. If the mouth is closed, the patient is nasally competent and nose breathing during sleep.
- This open area facilitates mouth breathing if the patient is nasally incompetent and sleeps with their mouth open.
- Opening and closing movements are permitted with the appliance in place
- The design of The Moses Express and the prescribed patient conditioning facilitate and teach how to *actively* maintain a more forward tongue posture in the mouth
- By deterring collapse of the tongue on the airway when the patient is asleep The Moses Express appliance treats mild to moderate obstructive sleep apnea.

Material Composition

- Upper component is identical to the upper component of The Moses[®] appliance and The Moses[®] Elite appliance; Dentsply Raintree Essix C+ polypropylene/ethylene copolymer (CAS Number 9010-79-1) customized vacuum formed retainer
- Customized vacuum form retainer will be added to cover the mandibular teeth – polypropylene/ethylene copolymer
- Body of the Moses Express will be made of:
 1. Dioshy TPE GP-0110M
CAS No. 26221-73-8 - Ethylene-1-octene copolymer (Trade name TPE) 100%
 2. Dioshy TPE-HP-990E-NC
 - A. CAS No. 66070-58-4 - Thermoplastic Elastomer (Trade name TPE) 64%
 - B. CAS No. 64742-54-7 – Lubricating Oil (Trade name 150N) 22%
 - C. CAS No. 9003-07-0 – Polypropylene Homopolymer (Trade name 6231-20) 9%
 - D. CAS No. 24937-78-8 – Ethyl-vinyl acetate copolymer (Trade name 3155) 5%
 3. Color additive:
CAS No. 57455-37-5 - Sodium alumino sulphosilicate 100%
- Advancement screw is not necessary in The Moses Express. Titration is achieved by reheating The Moses Express and reforming it in an altered maxillo-mandibular relationship using a different anterior bite guide.

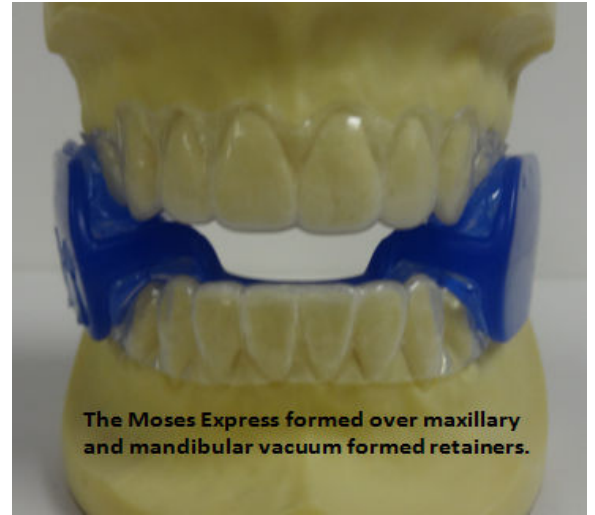
All materials are FDA and CAS approved as safe and biocompatible.

NOTE: Read all instructions before using The Moses Express appliance.

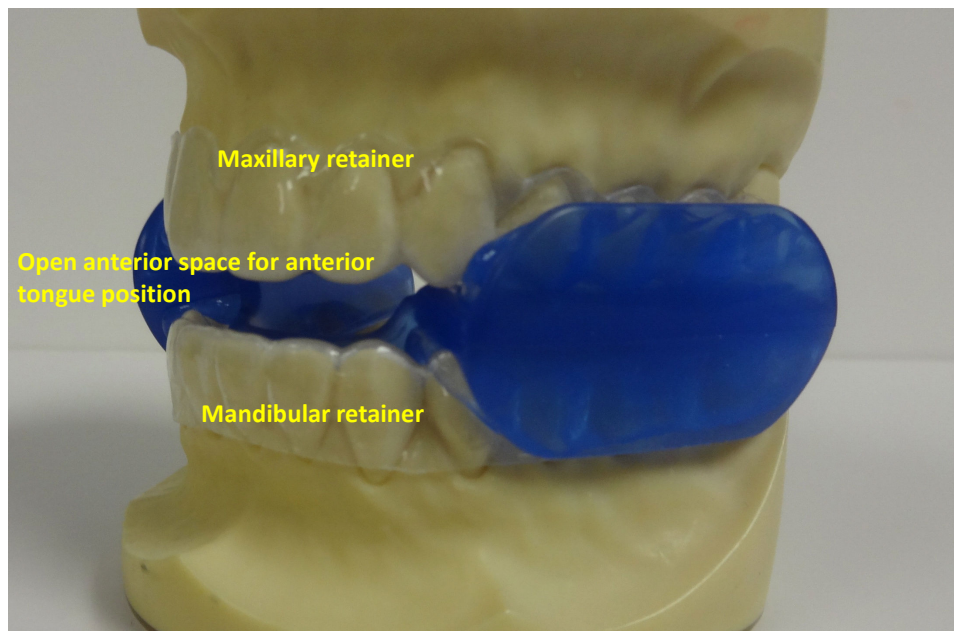
LABELLED PHOTOS OF THE MOSES EXPRESS APPLIANCE



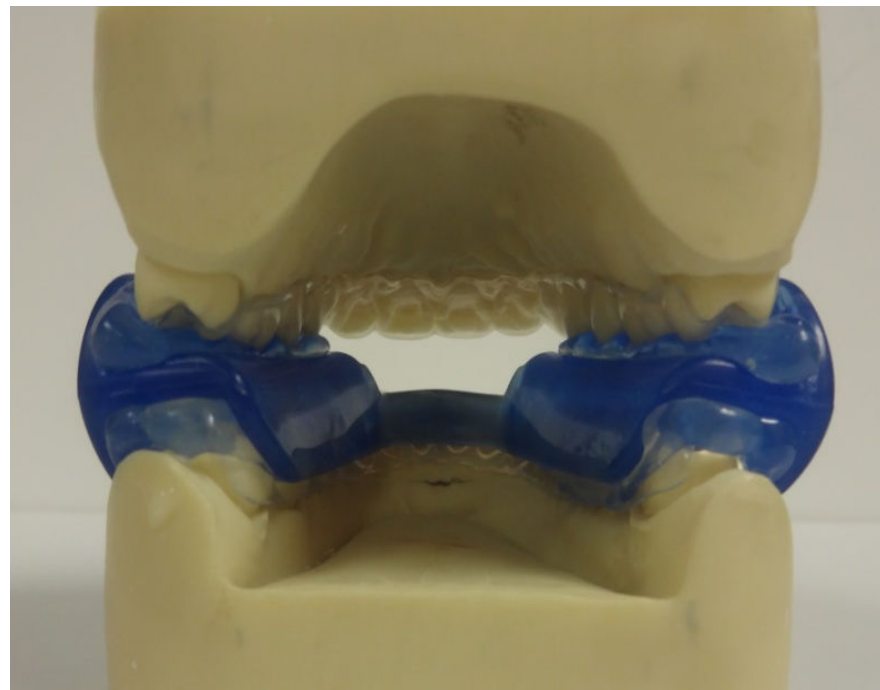
The Moses Express lower component formed over lower vacuum formed retainer.



The Moses Express formed over maxillary and mandibular vacuum formed retainers.



THE MOSES EXPRESS APPLIANCE, FRONT AND BACK VIEWS



WARNINGS

- This device is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea.
- If symptoms of breathing difficulty or other respiratory disorders exist or persist with or without use of The Moses Express appliance patient should contact you immediately.
- Patient may experience soreness or discomfort in their jaw or teeth. If the discomfort persists, the patient should contact you.
- First thing in the morning the patient may sense a change in their bite. This sensation should disappear within one hour. If it continues for more than two hours, instruct patient to chew a piece of sugarless gum for 15-30 minutes or until their back teeth are meeting. If they cannot get back to their old bite and experience pain or discomfort trying, they should contact you.
- Under normal circumstances the patient should **not** experience obstruction of oral breathing with The Moses Express appliance in their mouth. If the patient experiences breathing difficulty with The Moses Express appliance in place, the patient should consult their sleep physician.
- The patient should return to you, the dentist who fit the Moses Express appliance every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, the patient should contact you.

POSSIBLE SIDE EFFECTS

There are possible side effects associated with use of The Moses Express appliance. These side effects are not common. If the patient experiences any of the following side effects they should contact you, the doctor who prescribed and customized The Moses Express appliance.

- Slight tooth or gingival discomfort, due to pressure from the appliance
- Excessive salivation initially. This will improve as the patient becomes accustomed to wearing The Moses Express appliance.
- Slight jaw soreness or tightness initially that will ease with wearing the appliance
- Morning sensation of bite change. This will subside between 30 minutes and 2 hours after The Moses Express appliance is removed. If this perceived bite change persists longer, chewing a piece of sugarless gum will usually correct this problem. If it does not, the patient should contact you, the doctor who prescribed and customized The Moses Express appliance.
- Removing The Moses Express appliance while the patient is asleep. This usually stops after an adjustment period.
- Movement of teeth. Both the upper and lower are retainers. This would be a most improbable response. Should it occur, the patient should contact you, the prescribing doctor.
- Permanent bite change. This should not occur with a timely call to you, the prescribing doctor when the patient first notices this symptom.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, the patient should discontinue use and call you, the prescribing doctor immediately.

Prior to prescribing and customizing The Moses Express appliance for a patient, the dentist should consider the medical history of the patient including history of asthma, breathing or respiratory disorders or other relevant health problems. If a concern exists, the patient should be referred to the appropriate healthcare provider before prescribing and customizing the device.

ORAL APPLIANCE PROTOCOL

(I) Medical Assessment

- A) The patient sleeps with an FDA Class III HST and the report is analyzed and signed by a Board Certified Sleep specialist.
- B) If the patient has obstructive sleep apnea, a sleep specialist or the primary care physician is consulted relative to the best treatment modality. If an oral appliance is indicated in the opinion of the patient's physician, a work order for one is signed.
- C) A dentist with a written prescription for an oral appliance or written referral letter to the dentist with diagnosis expressed as part of a treatment plan, plus interpretation and summary report of sleep study, treats the patient with the oral appliance.

II) Dental Assessment

- A) History – medical and dental
- B) Examination by dentist
- C) Consultation and treatment plan
- D) Possible referral to original referrer or other medical specialist
- E) Written report

(III) Clinical Standards

The American Academy of Sleep Medicine has established as criteria for oral appliances to define successful treatment of obstructive sleep apnea syndrome:

- A) post-treatment Apnea-Hypopnea Index (AHI) 10 or below
- B) post-treatment AHI reduced by at least 50% from baseline AHI
- C) both criteria are met

- (IV) Clinical procedure
 - A) Baseline objective testing - polysomnogram
 - B) Maxillary and mandibular vacuum formed retainers, appliance customization of Moses Express appliance, delivery of Moses Express appliance
 - C) Patient signs informed consent, given appliance instructions and patient exercise regimen
 - D) Appliance adjustments
 - E) Completion of treatment, written letter to sleep specialist explaining results, and recommendation for follow-up polysomnogram

- (V) Periodic Evaluation
 - A) Six month recalls for two years following appliance fabrication to check effectiveness, fit, TMJ status and check for possible tooth shifting or bite change
 - B) Annual recall after initial one year period
 - C) A caries screening is recommended at all recalls

If neither clinical standard for success as described in (III) above is met, the patient protocol is as follows:

- 1) The old disinfected bite registration is checked.
- 2) If greater protrusion is possible or greater vertical dimension is required, a new position is used to recustomize the body of The Moses Express over the existing maxillary and mandibular vacuum formed retainers.

CLINICIAN NOTES:

VERTICAL: The correct vertical position at which The Moses Express appliance should be made is the maximum height the patient can tolerate and still comfortably close the lips. This usually does not change.

PROTRUSIVE: The correct horizontal bite position is the maximum painless position the patient can maintain. This position is different than "maximum comfortable protrusive". Patients will often assume a comfortable position that is less than the maximum painless protrusive. When the bite is being recorded on the anterior bite guide, the patient generates muscle forces to hold it in place while it sets.

MIDLINE DETERMINATION: The recorded bite is usually based on the upper incisor midline over the lower incisor midline. An alternative is upper arch centered directly over the lower arch. Often these are the same. When both alternatives do not coincide, the patient's comfort decides the choice. If the patient complains of unilateral pain when wearing The Moses Express it may be necessary to reheat and recustomize the interarch component in a corrected lateral position.

TECHNIQUE FOR FITTING THE MOSES EXPRESS APPLIANCE

1. **SEND IMPRESSIONS**, NOT MODELS. Impressions are needed so the lab can make separate models for the upper vacuum-formed retainers. The impression material must be polyvinyl siloxane or poly ether for replication in stone and shipping.
2. If preferred, dentists can pour impressions and make the maxillary and mandibular vacuum formed retainers in their office. Dentsply Raintree Essix C+ is recommended.
3. **From this point forward, the patient should be wearing their maxillary and mandibular vacuum formed retainers.**
4. **THE BITE** – Wooden tongue shims, the more hygienic plastic bite shims, bite guide sticks or any shim that can be stacked and/or stabilized anteriorly for the maxilla-mandibular registration are recommended for anterior arch positioning in the bite registration. If using wood, cut them to fit the anterior arch form. (From this point forward, we will refer to product of choice as “the shims”.)
5. The shims are placed for try-in between maxillary and mandibular teeth in the area of the incisors to the cuspids and must not interfere with lip closure.
6. The correct number of tongue blades is the maximum number the patient can fit, close on and comfortably seal the lips – in an **UNSTRAINED** lip closure. *Check lip muscles and mentalis and query the patient. “Can you comfortably keep your lips together or is that a strain to keep your lips closed?”*
7. With the first mixing tip on the bite registration extruder gun
 - a. Find the correct combination of vertical, midline and protrusive positions and record this position using a shim or shims.
 - b. Spread bite registration paste on the surface of one shim and insert behind the edge of the maxillary incisors.
 - c. Immediately tack the remaining blades together with small dots of bite registration material, spread bite registration material all over one surface insert on mandibular incisors.
 - d. Instruct the patient to bite into an edge-to-edge bite
8. Mark the midlines with a wax pencil.
9. Instruct the patient to slide the mandible forward to the maximum protrusive position that is not painful. *Using the words, “maximum comfortable protrusive” does not imply the same thing and they do not usually stretch as far.*
10. Mark a line on the tongue blades between the upper and lower segments in this position.
11. With the patient looking in a mirror instruct them to hold that exact position for 1 ½ minutes.

12. Extrude the bite registration paste, using a new mixing tip, between the posterior segments and overlap the front segment to hold everything together in a rigid one piece bite.
13. Trim the bite registration with a sharp scalpel removing what was soft tissue. Leave only the impressions of hard tissue in the bite.
14. DenMat Vanilla Bite and Kettenbach Futar are highly recommended as the bite registration materials.
15. A good desk scissors is the appropriate tool to cut and trim the wooden tongue depressors in step 3. Shims can be trimmed laterally on the lathe if necessary.
16. Try the Moses Express appliance in the patient's mouth on the mandibular arch with the lingual bar behind the anterior teeth. Position the anterior bite onto the maxillary anterior teeth. Ask the patient to bring their jaw a little forward and bite down, so their mandibular teeth are positioned in the groove on the bottom of the anterior bite. Now ask them to close their lips.
17. Remove the appliance from the patient's mouth. Now it is time to customize the appliance for your patient.
 - Supplies: Pot for heating water, 6 inches deep preferred
 - A thermometer that measures at least to 212° Fahrenheit
 - Timer, watch or clock with a second hand
18. Simmer water to 180-185° F.
19. Use tongs or a spoon to hold the mouthpiece in water for 60 seconds.
20. Position the anterior bite onto the maxillary anterior teeth. Leave the
21. Bite on the upper anterior teeth when the patient opens their mouth.
22. Like during practice, place the softened Moses Express appliance in the patient's mouth over the mandibular teeth with the lingual bar behind the mandibular anterior teeth.
23. With finger pressure, push down vertically onto the mandibular teeth. And then press lingually against the mandibular lingual flanges.
24. Ask the patient to bring their jaw a little forward and bite down, so their mandibular teeth are positioned in the anterior bite. They must be instructed to bite all of the way down until their teeth are firmly engaged in the anterior bite.
25. Now ask them to close their lips.
26. Instruct the patient to suck in with their lips and cheeks and push their tongue to the sides to form the softened material and achieve a snug fit over the teeth on the buccal and lingual.
27. Use finger pressure bilaterally against maxillary flanges or cheeks.
28. After 60 seconds, remove the appliance from the patient's mouth and run it under cold water.
29. Retry The Moses Express appliance to confirm snug fit.
30. If the fit is not snug, repeat above steps.

CLINICIAN ADJUSTMENT OF THE MOSES EXPRESS APPLIANCE

It is very important that patients be able to easily and smoothly insert and remove The Moses Express by themselves. Patients should be carefully queried to make sure the appliance is not irritating their soft tissue before they leave and instructed to come in immediately for adjustment if they develop a sore spot.

The Moses Express appliance is adjustable by the doctor for anterior mandibular movement. The old disinfected bite registration is checked. If greater protrusion is possible or greater vertical dimension is required, a new position is used to recustomize the body of The Moses Express over the existing maxillary and mandibular vacuum formed retainers.

The starting bite position for The Moses Express appliance is the maximum comfortable protrusive jaw position. It is recommended that patient comfort be a consideration in further anterior adjustment. As the patient wears The Moses Express appliance tight muscles may lengthen and ligaments may stretch. The appliance should never be recustomized to a position in which the patient is uncomfortable either wearing it or in the morning after awakening. Results of advancing the mandible anteriorly beyond the initial bite position should be monitored by objective measurement – a full polysomnographic study at a sleep lab.

PATIENT INFORMATION FOR USE WITH THE MOSES EXPRESS APPLIANCE

Prescription Use Only
Part 21 CFR 801 Subpart D

PRODUCT DESCRIPTION

The Moses Express appliance is a dental device in the category of mandibular advancement device. The Moses Express is a dual-layer oral mouthpiece. The inner layer softens in hot water, between 180-190°Fahrenheit and takes the shape of the posterior teeth for a snug comfortable fit. The outer layer remains stable in the simmering water and maintains the Moses Express' shape. It is customized to the patient's mouth based on the predetermined maxilla-mandibular relationship and is fit over maxillary and mandibular vacuum formed retainers. It is fit to the patient by a trained dentist.

The device characteristics of The Moses Express appliance are as follows:

- Maxillary and mandibular vacuum formed retainers (.3 mm thick)
- An interarch component, customizable to fit over the maxillary and mandibular teeth
- The prescribed protrusive jaw position is maintained by the labial flanges and by impressions of the maxillary and mandibular arches covered by retainers and processed into the interarch component
- By supporting the mandible in a protrusive jaw position, The Moses Express appliance passively advances the tongue
- There is an open area between the upper and lower cuspids vertically that is approximately 2-8 mm vertically.
- This open area is to facilitate a forward tongue position against the lips. If the mouth is closed, the patient is nasally competent and nose breathing during sleep.
- This open area facilitates mouth breathing if the patient is nasally incompetent and sleep with their mouth open.
- Opening and closing movements are permitted with the appliance in place
- The design of The Moses Express appliance and the prescribed patient conditioning facilitate and teach how to *actively* maintain a more forward tongue posture in the mouth

- By deterring collapse of the tongue on the airway when the patient is asleep The Moses Express appliance treats mild to moderate obstructive sleep apnea.

INDICATIONS FOR USE

The Moses Express appliance is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea.

DIRECTIONS FOR DAILY USE

Inspect your Moses Express appliance each day prior to use. If you notice any cracks or tears, contact your prescribing doctor.

1. Place the upper and lower retainers in your mouth first. Use your thumbs to firmly snap them over your upper and lower teeth.
2. Insert the interarch component, slide your lower jaw forward until you have engaged both arches in The Moses Express appliance.
3. Notice that when The Moses Express appliance is in place you can drink without removing the appliance.
4. When you remove The Moses Express appliance in the morning, remove the interarch blue component first, and then the upper and lower retainers.

WARNING: When the appliance is not in your mouth it should be stored dry in its container and kept in a drawer or medicine cabinet.

If you have pets (dogs or cats) it is a near certainty that they will chew up The Moses Express appliance if it is not stored properly.

HOMECARE INSTRUCTIONS

- Each morning after use, clean your Moses Express appliance with a denture cleanser. The recommended cleanser for The Moses Express appliance is **Kleenite**. Efferdent, Polident and store brand cleansers are acceptable but not as highly recommended.
- When you visit your prescribing doctor for your six month appliance check, it is recommended that you bring the appliance with you so the dentist can check your Moses Express appliance and clean it professionally in the ultrasonic cleaner.
- You should leave The Moses Express appliance in the denture cleanser for 10 – 15 minutes. Rinse it off and store it dry in its container.

NOTE: Leaving The Moses Express appliance in the denture cleanser for longer periods will not clean it better but may cause it to pick up a white soapy scum. Discoloration may occur but does not affect the quality or performance of your Moses Express appliance.

WARNING: Eating or drinking high sugar foods before inserting The Moses Express appliance could cause tooth decay and damage your teeth. Patients should always brush, floss and rinse before inserting the appliance for the night.

WARNINGS

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- You may experience soreness or discomfort in your jaw or teeth. If the discomfort persists, you should contact your doctor.
- First thing in the morning you may sense a change in your bite. This sensation should disappear within one hour. If it continues for more than two hours, you should chew a piece of sugarless gum for 15-30 minutes or until you're your back teeth are meeting. If you cannot get back to your old bite and experience pain or discomfort trying, contact your doctor.
- Under normal circumstances you should **not** experience obstruction of oral breathing with The Moses Express appliance in your mouth. If you do experience breathing difficulty with The Moses Express appliance in place, consult with your sleep physician.
- You should return to the doctor who fit you for The Moses Express appliance every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, contact your doctor for an appointment.

POSSIBLE SIDE EFFECTS

There are possible side effects associated with use of The Moses Express appliance. These side effects are not common. If you experience any of the following side effects you should contact the doctor who prescribed and customized The Moses Express appliance.

- Slight tooth or gingival discomfort, due to pressure from the appliance

- Excessive salivation initially. This will improve as you become accustomed to wearing The Moses Express appliance.
- Slight jaw soreness or tightness initially that will ease with wearing the appliance
- Morning sensation of bite change. This will subside between 30 minutes and 2 hours after The Moses Express appliance is removed. If this perceived bite change persists longer, chewing a piece of sugarless gum will usually correct this problem. If it does not, contact the doctor who prescribed and fitted The Moses Express appliance.
- Removing The Moses Express appliance while you are asleep. This usually stops after an adjustment period.
- Movement of teeth. Both the upper and lower are retainers. This would be a most improbable response. Should it occur, contact the prescribing doctor.
- Permanent bite change. This should not occur with a timely call to the prescribing doctor when you first notice this symptom.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, discontinue use and call your prescribing doctor immediately.

PACKAGING OF THE MOSES EXPRESS APPLIANCE

The Moses Express appliance is attainable by prescription only (RX ONLY). The Moses Express appliance will be sent to the prescribing dentist who will make the maxillary and mandibular vacuum formed retainers, customize the appliance over maxillary and mandibular vacuum formed retainers, and deliver the appliance to the patient.

The Moses Express appliance will be manufactured by:
Shun Hsiang Plastic Co., LTD. VAT NO.: 36119761
Address: No.25, Alley 16, Lane 1171, Sec. 1, Jhongshan Rd., Guanyin Township, Taoyuan country 328, Taiwan (R.O.C)
TEL.: +886-3-473-5689 FAX: +886-3-473-2966

The Moses Express appliance will be sent to prescribing dentist in a new labeled denture case sanitized and ready to be delivered to the patient. "Clinician Instruction Booklet" including "Patient Information" will be sent with The Moses Express appliance.



Copy of Shun Hsiang Plastic Co. Certificate of Registration ISO 9001:2008 is included in this section.



Certificate of Registration

This certificate has been awarded to

Shun Hsiang Plastic Co., Ltd.

No. 25, Alley 16, Lane 1171, Sec. 1, Jhongshan Rd., Guanyin Town,
Taoyuan County, Taiwan (R.O.C.)

in recognition of the organization's Quality Management System which complies with

ISO 9001:2008

The scope of activities covered by this certificate is defined below

Manufacture and Sales of Plastic Molding Injection Products and Parts

Certificate Number:

13321/A/0001/UK/En

Date of Issue: (Original)

17 February 2005

Date of Issue:

17 February 2014

Issue No:

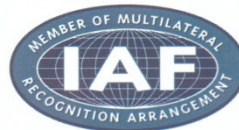
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Expiry Date:

16 February 2017

Issued by:

On behalf of the Schemes Manager



If there is any doubt as to the authenticity of this certificate, please do not hesitate to contact the Head Office of the Group on info@ros-group.com. URS is a member of Registrar of Standards (Holdings) Limited, Washington House, 3 Durlley Road, Bournemouth, BH2 5JQ, UK

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